Remarks/Arguments:

I. Introduction

Upon entry of the present amendment, claims 1-23 will be pending in this application. Claims 8, 12, 13, 15 and 18 have been amended to correct typographical errors. Claim 12 also adds an additional step to the claimed method, support for which appears in the specification at pages 6-7. No new matter has been added. New claims 22 and 23 have been added, support for which appears in the specification at least at pages 4-6 and 9. Based on the following remarks, Applicant respectfully requests reconsideration and allowance of the pending claims.

II. 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-4, 7, 10, 14-17, and 19-21 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,139,497 to Tilghman et al. The Examiner states that Tilghman discloses an orbital implant comprising titanium coated with polyethylene, which provides a smooth barrier surface, and that the Tilghman implant can be bent to conform to the shape of a defect. Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

First, Applicant disagrees with the Examiner's characterization that the Tilghman patent teaches titanium coated with polyethylene. The implant leaves of the Tilghman implant are described as coated with a sterilizable sheathing material, such as silicone rubber or compliant urethane compounds. *See e.g.*, Tilghman col. 4, ll. 45-48; col. 6, ll. 33-37. These materials are well-known as **thermoset** resins, and have quite different features than the claimed **thermoplastic** resins. Each family of materials has distinct processing and

application advantages and disadvantages. One primary distinction between thermoset and thermoplastic resins is that once a thermoset resin is heated and provided in its final shape, application of heat will *not* allow the material to soften and be re-shaped. By contrast, a thermoplastic resin *can* repeatedly be heated, softened, and molded, and it will then re-harden when cooled. The use of a thermoplastic resin in connection with this invention is particularly relevant when the primary method of manufacture used to make the implant (which involves the heating and melting of the components) is considered. *See e.g.*, pages 6-7 of the pending application.

In short, thermoset and thermoplastic materials are not interchangeable with one another, and there is no teaching or suggestion in the Tilghman patent that would lead one to seek to replace the thermoset resins described with a thermoplastic resin, as claimed. In fact, many thermoplastic resins are considered rigid materials. Only when they are fabricated as very thin sheets do they become flexible or displaceable by manipulation by hand. It would thus not be obvious to consider a typically rigid material (i.e., a thermoplastic resin) for covering a mesh construct in order to provide an implant that can be bent to fit a defect in a patient's bone.

Additionally, no other type of coating is described in connection with the Tilghman implant. This is primarily because the Tilghman coating is provided in order to *inhibit* soft and hard tissue ingrowth into the implant leaf portions. Silicone rubber and compliant urethane compounds are common implant materials to accomplish this function. For example, solid silicone rubber implants for facial, breast, and other implants are currently marketed by a number of companies. There is no teaching or suggestion in the Tilghman

patent, however, to replace these materials with a thermoplastic resin (such as polyethylene), as claimed. One potential reason for this is explicitly acknowledged by the Examiner – Tilghman does not seek to provide a porous surface, which *allows* ingrowth, as described in claims 5 and 6, and new claims 22 and 23.

Second, there is only one mention of polyethylene anywhere in the Tilghman patent – at col. 2, ll. 59. This portion of the background is discussing various alloplastic materials that have been used for orbital reconstruction. However, there is no disclosure or suggestion in the background or anywhere in the Tilghman patent of combining polyethylene with a surgical grade metal mesh as described and claimed in the present application.

As the Examiner knows, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See* MPEP § 2131; *Verdegaal Bros. V. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In this case, there is no express or inherent disclosure in Tilghman of the use of a thermoplastic resin with a metal mesh contained therein as presently claimed. As such, Applicant respectfully requests that this rejection be withdrawn.

III. 35 U.S.C. § 103(a)

A. Tilghman in view of Hayes

The Examiner has also rejected claims 5-6, 8-9, 11 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Tilghman et al. in view of U.S. Patent No. 6,031,148 to Hayes et al. The Examiner acknowledges that Tilghman fails to disclose a porous implant, but combines the disclosure of Tilghman with Hayes, which the Examiner suggests teaches the use of a porous implant for tissue ingrowth as well as a tissue growth barrier. The

Examiner's position is that it would have been obvious to combine Tilghman with Hayes[1] to arrive at the claimed invention in order to provide bone growth and healing to establish a functional implant. Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

First, the porous portion of the Hayes device is not a thermoplastic resin as claimed. Instead, it is "a mesh of fibers in either a random, unorganized configuration," "an organized fabric configuration ... comprised of threads, yarns, nets, knits, weaves, laces, or felts of fibers," or "an open cell foam structure that will allow tissue ingrowth." *See* Hayes, col. 4, ll. 23-43. Regardless of which option is chosen, the fibrous matrix that makes up the porous portion must of the Hayes device be a bioabsorable material. This is because the Hayes device is used to encourage the growth of periodontal bone into a cavity so that the new bone can support a dental implant to be drilled into new bone that is formed. It is not intended to remain in place indeterminately, but is intended to be degraded through either enzymatic, hydrolytic or other chemical reactions, into byproducts which are either integrated into or expelled from the body. There is no disclosure of the Hayes porous material being a thermoplastic resin (claim 1), or more specifically, a polyethylene (claim 7), or even more specifically, a high density polyethylene (claim 8). There is also no disclosure in Hayes of an *implant*, which is a surgical device that is intended to remain in place in the patient *without degrading*.

[1] The Examiner refers to a Myers patent at page 3 of the Office action, but because the rejection being made relates to the Hayes patent, we have assumed that this section intended to refer to Hayes throughout. To the extent that this assumption is incorrect, please clarify and indicate which patent is being cited.

In addition to the bioabsorable aspect of Hayes, it is also important to note that the Hayes device is used for guided tissue regeneration. In Hayes, guided tissue regeneration prevents soft tissue from growing into an area, and instead encourages bone growth (where, for example, a tooth was removed). The cell-barrier sheet prevents the growth of soft tissue, which grows more quickly than bone, and gives the bone time to regenerate. The porous portion (or the fibrous matrix) of Hayes allows ingrowth of tissue, which is used to stabilize the bioabsorable article at the desired location without using further securing means.

By contrast, one embodiment of the invention (e.g., the barrier embodiment of claims 3 and 4) provides a barrier surface that does not guide or encourage bone growth, but that is intended to prevent the growth of *any* tissue at all, whether hard (bone) or soft tissue. One seeking to provide an implant that, in some embodiments, completely prevents tissue ingrowth would not look to a reference that describes guided tissue regeneration using a bioabsorable article that degrades over time.

Additionally, even if the Tilghman and Hayes patents were combined, the claimed invention would not result. First, Hayes does not suggest the use of a metal mesh. If the mesh of the Tilghman patent were provided in connection with Hayes, the fibrous matrix (10) and cell-barrier sheet (12) of Hayes would be bioabsorable, leaving a metal mesh in place after time. Such a result would cause the Hayes device to be unacceptable for its intended purpose. (If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See In re Gordon,* 733 F.2d 900 (Fed. Cir. 1984)).

Second, if the porous portion of the Hayes device were applied to the Tilghman implant, there still would not be provided a metal mesh contained within a thermoplastic resin, as claimed. Instead, the metal mesh would be coated with a fibrous matrix of fibers or threads or an open cell foam. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw this rejection.

B. Tilghman in view of Melican

The Examiner has also rejected claims 12-13 under 35 U.S.C. § 103(a) as being unpatentable over Tilghman et al. in view of U.S. Published Application No. 2002/0120348 to Melican et al. The Examiner admits that Tilghman does not teach the use of a mold but submits that it would have been obvious to use the mold of Melican[2] to provide the implant of Tilghman for ease of manufacturing. Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

Again, Applicant notes that the implant of Melican is bioabsorable. *See* Melican abstract. Additionally, the materials used do not include both a metallic mesh and a thermoplastic resin, as recited by rejected claims 12-13. The reinforcement of Melican is a bioabsorable mesh (*see* ¶ 011) and the polymeric material is a bioabsorable polymeric foam component (*see* ¶ 010, 0024, 0044).

Moreover, the polymer solution that will eventually comprise the Melican foam is injected, poured, or placed into a mold set-up (comprised of the mold and the reinforcing element). Whereas the claimed invention applies **heat and pressure** to allow the

[2] The Examiner refers to an Iseki patent at page 3 of the Office action, but because the rejection being made relates to the Melican patent, we have assumed that this section intended to refer to Melican throughout. To the extent that this assumption is incorrect, please clarify and indicate which patent is being cited.

thermoplastic resin fines to partially melt and fuse to one another, the Melican application **cools** the mold set-up in an appropriate bath or on a refrigerated shelf (*see* ¶ 0052). Accordingly, even though a mold is used, the recited steps of claims 12-13 are not taught or described by Melican. Accordingly, even if the Tilghman and Melican references were combined, the claimed method steps are not disclosed or suggested. Applicant accordingly respectfully requests the Examiner to reconsider and withdraw this rejection.

IV. New Claims

Applicant has added new independent claims 22 and 23, which are intended to define the invention even more specifically. Although it would be incorrect to do so, to the extent that the Examiner maintains any of the rejections from the previous Office action in the next action, Applicant submits that these new claims should still be considered patentable and immediate allowance is respectfully requested. Support for these new claims appears in the specification at least at pages 4-6 and 9, as well as in originally-filed claims 3,5, 6, 7, and 9.

V. Declaration of Commercial Success

In addition to the above arguments, Applicant also submits the attached declaration of Greg Swords, describing the commercial success that has been experienced since the product described in this application has been marketed and sold. This evidence supports the secondary considerations of non-obviousness described in MPEP 2141 (*see* Graham v. John Deere, 383 U.S. 1 (1966)). As such, consideration of these facts is respectfully requested.

CONCLUSION

For at least the above reasons, Applicant respectfully requests allowance of the pending claims and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is invited to contact the undersigned at 404.815.6147.

Respectfully submitted,

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